Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K130301

1. Date of Submission: January 11, 2013

2. Sponsor

AUG 2 2 2013

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3. Submission Correspondent
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4. Proposed Device Identification

Trade Name: 1). REDLEAF, Elimedical, and
2) Multiple or Customers' Trade Name
Device Name: Latex Surgeon's Gloves (Powdered and Powder Free)
Common Name: Surgical Gloves

Classification: I
Product Code: Surgeon's Glove - 79KGO
Classification Name: surgeon's gloves
Regulation Number: 21 CFR 878.4460
Review Panel: General & Plastic Surgery

Intended Use Statement:
A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

5. Predicate Device Identification

510(k) Number: k063757
Product Name: Motex Powder-Free Surgical Gloves & Powdered Latex Surgical Gloves
Manufacturer: SHANGHAI MOTEX HEALTHCARE CO., L TD.

6. Device Description

The proposed device, Latex Surgeon's Gloves (Powdered and Powder Free) is a sterilized and disposable medical glove intended to be worn by operating room personnel to protect a surgical wound from contamination.

The proposed device is made of natural rubber latex, per standard ASTM D3577-09^{e1}, the rubber surgical gloves classification is:
"Type 1 - gloves compounded primarily from natural rubber latex".

The proposed device include Powdered and Powder Free Latex Surgeon's Gloves, and variations of different size. All variations share the same colour, creamy white.

The proposed device is provided radiation sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and place in a sterility maintenance package to ensure a shelf life of 3 years.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM D3577-09^{e1}, Standard Specification for Rubber Surgical Gloves.
ASTM D 5151-06 (Reapproved 2011), Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-06 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves.
ASTM D5712-10, Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method.
ASTM D6499-07, Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and Its Products.
ASTM F1929-98 (2004), Standard Test Method for Detecting Seal Leaks in Porous Medical

Packaging by Dye Penetration.
ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ISO11137-2: 2006, Sterilization of healthcare products-Radiation-Part2: Establishing the sterilization dose.

8. Substantially Equivalent Comparison Conclusion

Table III-1 Substantially Equivalent Comparison

ITEM	Proposed Device	Predicate Device (k063757)
Product Code	KGO	Same
Regulation No.	21 CFR 878.4460	Same
Class	I	Same
Intended Use	A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	Similar
Powdered or Powered free	Powdered, and Powered free	Same
Classification per ASTM D3577	Type 1 - gloves compounded primarily from natural rubber latex	Same
Dimensions	Size 6, 6 $^1/_2$, 7, 7 $^1/_2$, 8, 8 $^1/_2$, 9 Dimensions comply with ASTM D3577	Same
Physical Properties	Comply with ASTM D3577	Same
Freedom from Holes	Comply with ASTM D3577 and ASTM D5151	Same
Powder Content	Comply with ASTM D3577 and ASTM D6124	Same
Protein Content	Comply with ASTM D3577, ASTM D5712 and ASTM D6499	Same
Biocompatibility	Comply with ISO 10993-10	Same
Sterilization	Radiation SAL: 10^{-6}	Same
Label and Labeling	Meet FDA's Requirements	Same

Difference in intended use between the proposed and predicate device is discussed in the 510(k) submission documents, it is concluded that the difference will not affect the effectiveness and safety of the proposed device.

The proposed device, Latex Surgeon's Gloves (Powdered and Powder Free), is determined to be Substantially Equivalent (SE) to the predicate device, Motex Powder-Free Surgical Gloves & Powdered Latex Surgical Gloves (k063757), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

EliMedical Devices (Fujian) Incorporated
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
P.O. Box 237-023,
Shanghai, China 200237

Re: K130301
Trade/Device Name: Latex Surgeon's Gloves (Powdered and Powder Free)
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: KGO
Product Code: I
Dated: July 5, 2013
Received: August 2, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number: K130301

Device Name: Latex Surgeon's Gloves (Powdered and Powder Free)

Indications for Use:

A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

☐PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☒OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sreekanth Gutala -S
2013.08.22 11:47:44 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130301